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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/304,564	05/04/1999	MOHAMED CHOKRI	USD-93-AG-ID	9853

466 7590 12/18/2002

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/304,564

Applicant(s)

CHOKRI ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. In view of arguments presented in the Appeal Brief filed on April 1, 2002,
PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following
two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37
CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a
supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or
other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections Maintained and New Grounds of Rejection:

2. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the
subject matter which applicant(s) regard as their invention. Evidence that claims 3-5 fail(s) to
correspond in scope with that which applicant(s) regard as the invention can be found in Paper
No. 7 filed January 4, 2001. In that paper, applicant has stated that the claimed macrophages are
distinguished over the prior art and have the unique properties recited in the claims because of
the incubation medium used, and this statement indicates that the invention is different from
what is defined in the claim(s) because the claimed methods do not recite macrophages that were
incubated in any specific medium.

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3. Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chokri (Chokri, M. et al., Res. Immunol., 143: 95-99, 1992).

Chokri teach a method of treating tumors by administration of macrophages and bispecific antibodies that recognize both the FcγRI of macrophages and recognizes human adenocarcinoma antigen (see abstract). The macrophages increase cytotoxic activity compared to standard macrophages by about 20-40 percent in the presence of interferon-gamma (see Table II, page 98). Chokri teaches precoating the macrophages with bispecific antibodies (preincubation of macrophages) and simultaneous administration of macrophages and bispecific antibodies (see page 97, 2nd column). Thus, Chokri teaches methods that are the same as that claimed.

4. Claims 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Fanger (U.S. Patent 5,635,600; issued June 3, 1997; effective filing date Feb. 2, 1988).

Fanger discloses method of treating cancer by administering bispecific antibodies and macrophages (col. 5, lines 17-28, and col. 5, line 61-col. 6, line 27), where the macrophages may be armed with bispecific antibodies (reads on simultaneous administration and preincubation of macrophages with bispecific antibodies). The macrophages may be treated with interfereon-gamma. Absent evidence to the contrary, the macrophages of Fanger will exhibit the same characteristics that are listed in claim 3 for activation of macrophages by interferon-gamma. Thus, Fanger discloses methods that are the same as that claimed.

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5. Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Medarex (WO 91/05871; published May 2, 1991).

Medarex teaches method for treating cancer by administering bispecific antibodies and macrophages (page 5, lines 5-21; page 6, line 19 to page 7, line 3), where the macrophages may be armed with bispecific antibodies (reads on simultaneous administration and preincubation of macrophages). The macrophages may be treated with interferon-gamma. Absent evidence to the contrary, the macrophages of Medarex will exhibit the same characteristics that are listed in claim 3 for activation of macrophages by interferon-gamma. Thus, Medarex teaches methods that are the same as that claimed.

Double-Patenting:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 3-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 5,662,899. Claims 3-5 are drawn to methods for treating cancer comprising administering macrophages and bispecific

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antibodies. Claims 1 and 12 are drawn to macrophages, and methods of treatment comprising administering macrophages, where the macrophages appear to be the same as those of claims 3-5 in view of the arguments presented in the Appeal Brief, setting forth the position that the recitation of how the macrophages are prepared is not limiting to the scope of the claimed macrophages in U.S. Patent 5,662,899. Claims 1 and 12 differ from the instant claims in that the claims 1 and 12 of U.S. Patent 5,662,899 are not drawn to methods where bispecific antibodies are administered. However, claim 12 is drawn to a method of treatment comprising administering macrophages. Co-administration with bispecific antibodies is within the scope of claim 12, and co-administration with bispecific antibodies is a species that is specifically contemplated in the specification and therefore, is an obvious species of the genus of claim 12.

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH
Anne L. Holleran
Patent Examiner
December 12, 2002


ANTHONY G. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER